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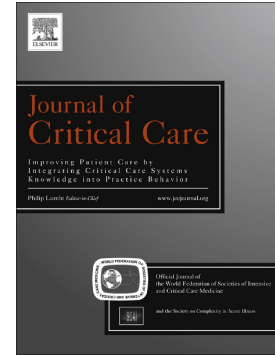
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Validation of the critical-care pain observational tool (CPOT) for the detection of oral-pharyngeal pain in critically ill adults

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TITLE: Validation of the Critical-Care Pain Observational Tool (CPOT) for the detection of oral-pharyngeal pain in critically ill adults

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1. Introduction

Inadequate recognition and treatment of pain remains a significant problem for patients in the intensive care unit (ICU) [1]. Up to 50% of ICU patients recall moderate to severe pain, both at rest and during commonly performed procedures [2]. This finding suggests healthcare professionals often underestimate pain associated with daily care procedures including tracheal suctioning, physical repositioning, and wound care [3]. Pre-emptive pain management is important as common ICU procedures can produce a twofold increase in pain from baseline [4]. Yet, as few as 5% of patients receive pre-emptive analgesia for procedures such as tracheal suctioning, recalled as one of the most painful procedures in the ICU [5]. Consequences of poor pain control include increased duration of mechanical ventilation, infection, ICU length of stay, 30-day mortality, and treatment costs [6-8].

Recent ICU studies identify common oral procedures as underappreciated sources of pain [9,10]. During mechanically ventilation, instruments are routinely inserted into the oral-pharyngeal space for secretion management, oral-dental hygiene, and application of ventilator-associated pneumonia (VAP) prophylaxis including chlorhexidine and selective oral decontamination [11]. Routine oral procedures may exacerbate pain associated with the endotracheal tube due to movement [12,13]. Moreover, emergent oral health problems such as xerostomia, mucositis, candidiasis, and device-related pressure injury may induce procedural pain [14]. In inflammatory states (e.g., oral mucositis), peripheral nociceptors display a lower threshold for stimulation-induced pain, a condition known as hyperalgesia, thereby complicating routine oral procedures [15].

Behavioral responses (e.g., grimacing, biting, and localizing) during oral procedures may indicate unmanaged pain. Therefore, oral-pharyngeal pain assessment and management is an

important target for practice improvement [16]. Despite the importance of pain assessment, clinicians may have difficulty detecting oral-pharyngeal pain, especially in patients unable to self-report [17]. The Critical-Care Pain Observational Tool (CPOT) is one of the most valid and reliable behavioral pain scales for use in non-verbal ICU patients [18]. However, the CPOT previously was not validated to detect presence of oral-pharyngeal pain among critically ill adults during routine oral care procedures. Therefore, our research objectives were to examine:

1. The relationship between CPOT scores and patient self-report of oral-pharyngeal pain (criterion validation);
2. Changes in CPOT scores at rest and during one non-painful and three potentially painful oral procedures (discriminative validation); and
3. Inter-rater reliability of CPOT scoring during oral care procedures.

2. Materials and methods

2.1 Design and setting

We conducted a prospective observational study in two ICUs, one a mixed medical-surgical-trauma ICU and the other a cardiovascular surgery ICU at Sunnybrook Health Sciences Centre, a tertiary academic centre in Toronto, Canada. Eligibility criteria included: (a) adults 18 years and older; (b) admitted to ICU for >24 hours and < 4 weeks; (c) intubated or tracheostomised; and (d) able to understand English for those capable of self-report. Exclusion criteria included: (a) quadriplegia; (b) treatment with neuromuscular blocking agents; (c) a score of -5 (unarousable) on the Richmond Agitation Sedation Scale [19]; (d) delirium detected using the Intensive Care Delirium Screening Checklist [20]; (e) suspected brain death; and (f) a condition not permitting routine oral care such as mandibular fractures requiring fixation. Recruitment was stratified by level of consciousness i.e., (i) Glasgow Coma Score (GCS) of 4-8 (unconscious but able to

move); (ii) GCS score of 9-12 (conscious but likely unable to self-report); and (iii) GCS score of 13-15 (conscious and likely able to self-report by non-verbal means) [21].

The participating hospital and University of Toronto research ethics boards approved the study. Written informed consent was obtained from the patient or surrogate decision-maker prior to study enrolment.

2.2 Procedures

A trained research team member screened the study ICUs daily for eligible patients and obtained informed consent. Three pain raters underwent a 90-minute training session incorporating rating of standardized patient videos previously used in CPOT validation studies prior to commencement of data collection [22]. For each patient, two independent raters scored the CPOT: (a) at rest; (b) during a non-painful procedure i.e., gentle touch; and (c) three potentially painful oral procedures: oral suctioning for secretions using a Yankauer tip device; manual tooth brushing; and oral swabbing with a sponge toothette. Bedside nurses performed routine oral care according to unit standards.

2.3 Instrument

The CPOT includes four behavioural domains: a) facial expression; b) body movements; c) compliance with ventilator (for mechanically ventilated patients) or vocalization (non-ventilated patients); and d) muscle tension. Each component is scored from 0 to 2 for a possible total score ranging from 0-8. A score of > 2 indicates presence of pain [18], however, the CPOT does not give an indication of pain intensity.

2.4 Self-report of pain

Patients with a GCS ≥ 13 were asked if they experienced pain during each oral care procedure (yes/no) and to rate their pain intensity with the 0-10 numeric rating scale (NRS) by non-verbal means including mouthing words, writing, pointing or head nodding.

2.5 Sample size and Data analysis

To assess criterion validation, we required a sample of 46 participants able to self-report (GCS 13-15) to achieve 80% power, based on a two-tailed test and an alpha of 0.05. For discriminative validation, we required 15 participants in each of the three strata defined by GCS scores to provide 80% power to detect a 2-point difference in CPOT scores, based on a two-tailed test and an alpha of 0.01. For inter-rater reliability, assuming an intraclass correlation coefficient (ICC) of .40 or higher for two raters, we required a sample size of 45 to achieve 80% power, based on a two-tailed test and an alpha set at 0.05. Based on the needs for 46 participants able to self-report and 30 participants at GCS levels less than 13 we targeted a minimum sample size of 76.

Participant characteristics were summarized using means and standard deviations and counts and proportions. We calculated mean CPOT and NRS scores across raters for each painful exposure separately and performed Receiver Operating Characteristic (ROC) curve analyses to assess accuracy of the CPOT for detecting pain (score >2) compared to the NRS (score ≥ 4) [6,23,24]. We used repeated measures ANOVA to assess change in CPOT scores across painful and non-painful exposures in patients stratified according to the 3 levels of consciousness described above, with exposure type as the within factor and level of consciousness as the between factor. We tested for interaction between exposure type and consciousness level. To further assess discriminative validation, we used multiple linear regression to compare mean CPOT scores for a painful oral procedure among participants who received an intravenous opioid

≤ 1 hour of the painful exposure with scores from participants not receiving intravenous opioids adjusting for age, sex, admission category and SOFA score [25]. To test inter-rater reliability, we calculated ICCs between raters for total CPOT score of each exposure and CPOT domains using a one-way random effects model due to use of different combinations of raters.

3. Results

We recruited 98 participants with a mean age of 61.2 (SD 19.7). Most participants were male (63.3%) and had an oral endotracheal tube (92.9%); mean length of stay in the ICU at time of observation was 6.6 days (SD 0.6). Most (78.1%) received an opioid, sedative or antipsychotic within four hours of the painful exposures; 46.9% received an intravenous opioid at the time of, or within an hour of the painful exposure (Table 1). The proportion of patients with CPOT scores >2 indicating pain presence during oral procedures were: oral suction (42.9%); swabbing with toothette (38.7%); and tooth brushing (29.7%).

--Insert Table 1 about here--

3.2 Criterion validation

Table 2 presents the AUCs for the accuracy of the CPOT to detect pain presence (score >2) compared to NRS scores (score ≥ 4) for each oral care procedure. Accurate pain detection with the CPOT was found for tooth brushing (AUC=.80; 95% CI .54-1.00) and oral suctioning (AUC=.72; 95% CI .54-.91) but not toothette swabbing (AUC=.68; 95% CI .42-.94) (Figure 1).

--Insert Table 2 & Figure 1 about here--

3.3 Discriminative validation

We found a significant within-subject effect for exposure type ($F=106.9$; $P<.001$). There was no difference in CPOT scores rated for rest and the non-painful exposure and higher CPOT scores for all painful exposures (all $<.001$). Level of consciousness did not influence CPOT

scores ($F=2.75$; $P=.07$), but the interaction between exposure and level of consciousness was statistically significant ($F=4.71$ $P<.001$). CPOT scores for the 3 potentially painful oral care exposures were lower in participants with GCS 13-15 compared to the unconscious (GCS 4-8) and altered consciousness groups (GCS 9-12) (Table 3).

--Insert Table 3 about here--

We found mean CPOT scores were lower among participants who received intravenous opioid at or within an hour before the potentially painful exposure; however, differences were not significant. (Table 4).

--Insert Table 4 about here--

3.4 Inter-rater reliability

Inter-rater reliability was excellent for total CPOT scores ($ICC=.78-.91$). Inter-rater reliability lowest ICCs were identified for the CPOT domain of ventilator compliance during tooth brushing ($ICC=.41$) and highest ICCs for the body movement domain across all exposure types ($ICC=.86-.88$) (Table 5).

--Insert Table 5 about here--

4. Discussion

Our results confirm the validity and reliability of the CPOT for detecting pain presence associated with tooth brushing and oral suctioning, but not for toothette swabbing. We found pain to be present using the CPOT for 43% of patients during oral suctioning, 39% during toothette swabbing, and 30% during tooth brushing. Prior studies demonstrate endotracheal tube suctioning to be amongst the most painful procedures reported by patients [5,26]. We found oral suctioning also induces pain. Use of oral suction catheters, especially at high vacuum pressures, may cause tissue trauma resulting in pain. Similarly, tooth brushing may generate or exacerbate

pain accompanying poor oral health states [27,28]. Although patients able to self-report (GCS 13-15) did not regularly report pain during toothette swabbing, it is possible that ICU patients with lower GCS scores will experience discomfort during this procedure. Oral swabbing may not be uniformly painful due to the pliability of the sponge tip toothette, especially when moistened.

We found good discriminative validation of the CPOT for detecting pain presence regardless of level of consciousness. The lower CPOT scores found in patients with higher consciousness (GCS 13-15) may reflect a patient's ability to cooperate during oral care, thereby reducing motor tension, which may exacerbate pain [29]. We found excellent inter-rater reliability of total CPOT scores though, as with prior studies, we obtained lower inter-rater reliability scores during rest and non-painful exposures, suggesting the CPOT is more reliable when assessing face and body movement, in response to therapeutic procedures [22].

The ability to detect oral-pharyngeal pain is important as over 50% of mechanically ventilated patients exhibit reactive behaviours (e.g., mouth closing and biting) during oral interventions. Failure to assess or treat pain in the 4 hours immediately preceding an oral procedure is independently associated with difficulty accessing the oral cavity [11]. Reactive behaviors during oral procedures may impede preventative hygiene, thereby leading to oral health deterioration and discomfort [16]. Unrecognized pain may also increase nursing workload and result in adverse events [30,31].

Common characteristics of ICU patients including advanced age, low socioeconomic status, comorbidity, reduced salivary production, and retained natural teeth places them at risk of oral-pharyngeal pain during mechanical ventilation [32]. Prevalence of painful conditions such as caries and periodontal disease increases with age and comorbidities such as diabetes [33]. Access to preventative and restorative dental care becomes more difficult for older adults, for a variety of

reasons such as loss of dental insurance coverage, adding to additional pain risk [34]. As the numbers of patients requiring invasive mechanical ventilation is growing internationally, especially among older adults, ICU clinicians need effective tools to assist in the identification and management of patients at risk of oral-pharyngeal pain [35,36].

The clinical impact of the CPOT adoption into practice demonstrated in previous studies includes increased frequency of pain assessments, better identification of pain, reduction in the use of deliriogenic sedatives, and fewer adverse events [37]. As it relates to procedural pain during oral care, the CPOT may enhance clinician ability to recognize behaviors typically considered pain-related (e.g., facial grimacing) in addition to others less obvious (e.g., pulling at tubes, attempting to sit up, not following commands) [3]. Better pain identification and management may reduce pain-related complications associated with invasive mechanical ventilation including self-extubation [6]. Finally, the CPOT offers a tool to assess oral-pharyngeal pain as an outcome for future interventional trials of oral care tools, protocols, and treatments including selective oral decontamination.

4.1 Strengths and limitations

Strengths of this study include an adequate sample size, standardization of data collection using trained pain raters, and inclusion of ICU patients with diverse diagnoses and levels of consciousness. Limitations include the inability to blind raters to the painful procedure. Although raters were trained not to observe each other's scores, there is some potential they may have influenced one another.

5. Conclusion

This study demonstrated the CPOT to be valid and reliable for the detection of oral-pharyngeal pain during tooth brushing and oral suctioning procedures in intubated and tracheostomised adults. The CPOT showed excellent criterion validation, discriminative validation, and inter-rater reliability. As pain associated with an endotracheal tube and oral health deterioration is common during mechanical ventilation, regular oral-pharyngeal pain assessment and management may improve patient experiences and treatment outcomes.

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INSTITUTION

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CONFLICT of INTEREST

The authors have no conflicts of interest to declare.

AUTHOR CONTRIBUTIONS

Conception and design of the study: CD, VP, CG, LR; Data acquisition, CD, LR; analysis and interpretation of data: CD, VP, CG, LR; Drafting the article or revising it critically for important intellectual content: all authors. CD is the guarantor of the paper, taking responsibility for the integrity of the work as a whole, from inception to published article.

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Table 1. Demographic Characteristics of Sample (n=98)

N = 98	n (%)
Age, mean (SD)	61.2 (19.7)
Sex	
Male	62 (63.3)
Days in ICU, mean (SD)	6.6 (0.6)
Admission categories	
Medical	38 (38.8)
Surgical	25 (25.5)
Trauma	35 (35.7)
Airway	
Tracheostomy	7 (7.1)
Endotracheal tube	91 (92.9)
Type of breathing device	
Ventilator	92 (93.9)
Tracheostomy mask	6 (6.1)
Physical restraint	69 (70.4)
SOFA score	5.70 (2.6)
Opioid, sedation or antipsychotic in last 4 hours	75 (78.1)
Intravenous opioid in last hour	45 (46.9)

Table 2. Receiver Operator Analyses of COPT Scores compared to Self-Reported Pain^a

	Toothette swabbing with (n=48)	Tooth brushing (n=38)	Oral suction (n=48)
n(%) CPOT >2	9 (18.8)	8 (21.1%)	14 (29.2%)
n(%) NRS \geq 4	6 (12.5%)	4 (10.5%)	11 (22.9%)
AUC (95% CI)	.68 (.42-.94)	.80 (.54-1.00)	.72 (.54-.91)

^aSample size based on self-reporters with data on each pain scale

COPT = Critical-Care Pain Observation Tool. NRS = Numerical Rating System. AUC=Area Under the Curve. CI = confidence interval.

Table 3. CPOT Scores Across Varying Exposures and Levels of Consciousness

	Rest	Gentle touch	Toothette swabbing	Tooth brushing	Oral suction
	CPOT (SD)	CPOT (SD)	CPOT (SD)	CPOT (SD)	CPOT (SD)
GCS 4-8 (n=12)	.29 (.72)	.42 (.70)	3.29 (1.45)	2.54 (1.59)	2.87 (1.69)
GCS 9-12 (n=18)	.17 (.34)	.33 (.49)	2.97 (1.32)	2.42 (1.23)	2.64 (1.43)
GCS 13-15 (n=46)	.46 (.71)	.46 (.66)	1.88 (1.32)	1.63 (1.28)	2.25 (1.34)
Overall (n=76)	.36 (.65)	.42 (.62)	2.36 (1.47) ^a	1.96 (1.37) ^a	2.44 (1.43) ^a

^aSignificant difference (<.001) compared to the exposure of rest

COPT = Critical-Care Pain Observation Tool Score. SD = Standard Deviation. GCS = Glasgow Coma Score

Table 4. Regression analysis of CPOT Scores and Recent Intravenous Opioid Intake^a

	Swabbing with toothette (n=95)		Tooth brushing (n=78)		Oral suction (n=93)	
	B (SE)	P value	B (SE)	P value	B (SE)	P value
Received Opioid IV ^b	-.59 (.36)	.10	-.20 (.37)	.59	-0.07 (.34)	.84

^aControlling for Age, Sex, Admission Category and SOFA score^bReceived opioid IV < one hour of observation

SE= Standard Error

Table 5. Measures of Inter-Rater Reliability for CPOT Domain-Specific and Total Scores Across Exposures

	Rest (n=98)	Gentle touch (n=98)	Toothette swabbing (n=98)	Tooth brushing (n=78)	Oral suction (n=96)
CPOT Domains	ICC (P)	ICC (P)	ICC (P)	ICC (P)	ICC (P)
<i>Facial Expression</i>	.49 (.001)	.68 (<.001)	.76 (<.001)	.76 (<.001)	.86 (<.001)
<i>Body movement</i>	.85 (<.001)	.80 (<.001)	.88 (<.001)	.88 (<.001)	.86 (<.001)
<i>Ventilator Compliance</i>	--- ^a	1.00	.75 (<.001)	.41 (.011)	.81 (<.001)
<i>Muscle tension</i>	1.00	--- ^a	.65 (<.001)	.55 (<.001)	.71 (<.001)
<i>Total</i>	.78 (<.001)	.79 (<.001)	.90 (<.001)	.88 (<.001)	.91 (<.001)

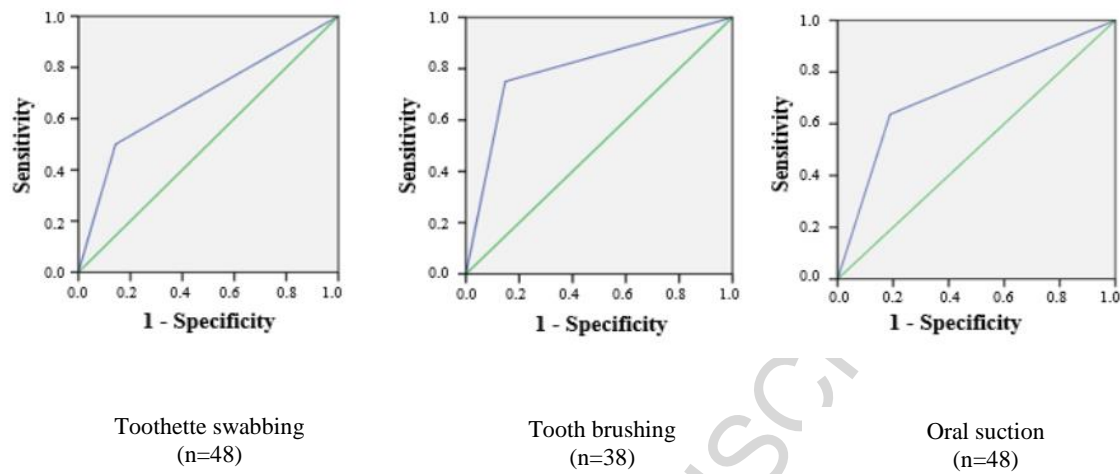
^ainsufficient variance to calculate; 99% agreement

COPT = Critical-Care Pain Observation Tool

ICC = intraclass correlation coefficient

P = P value

Figure 1. ROC Curves of Accuracy of CPOT-Assessed Pain Presence Against NRS-Assessed Pain Presence



COPT = Critical-Care Pain Observation Tool. NRS = Numerical Rating Scale. ROC= Receiver Operating Characteristic

Highlights

- Procedural pain is common in mechanically ventilated patients
- Routine oral procedures incite reactive behaviors $\geq 50\%$ of intubated patients
- We tested the Critical-Care Pain Observational Tool's ability to detect oral pain
- The Critical-Care Pain Observational Tool's can reliably detect procedural oral pain
- Oral procedures are painful for a substantial number of patients